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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SCHELL, LAURA C	

ART UNIT	PAPER NUMBER
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/753,979	BRADY ET AL.	
	Examiner	Art Unit	
	LAURA C. SCHELL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-8 and 11-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-8 and 11-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 6, 8, 11, 12 and 16-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elsberry et al. (US Patent No. 5,603,703) in view of Thomas (US Patent No. 5,342,383) and further in view of Rosenman et al. (US 2006/0084943). Elsberry discloses a system comprising a hollow rigid tube (Fig. 1, 16; col. 3, lines 18-19), including a proximal end (above element 12, near 14) and a distal end (near 20) and a lumen extending there between, wherein the hollow tube is shaped and sized to permit insertion into a lumen of a flexible tubular infusion catheter (element 18; col. 1, lines 9-13; col. 3, lines 56-59; col. 5, lines 6-18 all disclose that while the title of the invention is directed towards aspiration, the invention can be used for infusion, and thus

is also an infusion catheter), and wherein the hollow tube is stiffer than the infusion catheter (col. 4, lines 29-31 disclose that a rigid stylet is used to add rigidity to the stylet/catheter combination, which means that the stylet is inherently stiffer than the catheter, otherwise a rigid stylet wouldn't be needed) such that the hollow tube acts as a stylet for guiding the catheter through tissue to a target location.

Elsberry further discloses that the lumen of the hollow tube is filled with a fluid, and in which the proximal end of the hollow tube is configured to be closed to retain the fluid within the lumen of the hollow tube (col. 4, lines 56-66). Elsberry also discloses that a fluid reservoir is coupled to the proximal end of the hollow tube (col. 3, lines 42-44). Elsberry also discloses that the hollow tube and the fluid reservoir are sized to hold enough fluid to fill the lumen of the infusion catheter after withdrawal of the hollow tube from the lumen of the infusion catheter (col. 3, lines 56-66). Elsberry further discloses a flexible tubular infusion catheter (18) including a proximal end (near 12) and a distal end (near 20) and a lumen extending there between, the lumen of the infusion catheter sized and shaped to permit insertion of the hollow tube therein (see Fig. 1). Elsberry further discloses that the proximal end of the infusion catheter sealingly engages around the hollow tube when a portion of the hollow tube is located within the lumen of the infusion catheter (22 forms a seal around 16, alternatively see Fig. 4). Elsberry also discloses that the lumen of the catheter includes a diameter having at least two different values at different locations along the lumen of the catheter (Fig. 3 discloses that the catheter, here 26, has tow different diameters, a larger diameter near the holes (28) and

a smaller diameter near the tip). Elsberry also discloses means for temporarily sealing the proximal end (12) of the hollow tube to retain fluid within the hollow tube.

Elsberry further discloses a method comprising loading a hollow-tube stylet with fluid (col. 8, line 64); inserting the stylet into a lumen of a flexible infusion catheter to provide enough stiffening to the catheter to guide the catheter through living tissue toward a target (col. 8, lines 51-52 and lines 65-67); directing the stylet and the catheter through tissue to the target (col. 4, lines 30-37; please note that in each claim, the phrase "as the hollow rigid tube is tunneled through tissue" is functional language, and the device disclosed by Elsberry if capable of performing the function of tunneling, especially as it is well known in the art that a catheter that first enters the vasculature must first be tunneled through the skin, fat and tunnel into the vessel in order to enter the vasculature); and withdrawing the stylet from the catheter, in which the withdrawing includes releasing the fluid from the stylet into the lumen of the catheter to avoid air form occupying the lumen of the catheter upon withdrawal of the stylet (col. 9, lines 1-2 and claim 35). Elsberry further discloses temporarily closing a proximal end of the stylet, after loading the stylet with fluid, to assist in retaining the loaded fluid within the stylet (col. 4, lines 65-67). Elsberry further discloses opening the proximal end of the stylet after inserting the stylet into the lumen of the catheter and before withdrawing the stylet, to release fluid from the stylet into the lumen of the catheter and further including infusing a fluid agent through the catheter after withdrawing the stylet (claims 31 and 35).

Elsberry, however, does not disclose that the hollow rigid tube (stylet) has a remotely detectable locator positioned on the tube allowing the stylet to be tracked by a positioning system for proper positioning of the catheter within the patient's body. Thomas, however, discloses a stylet having a radiopaque material at the tip allowing the stylet to be tracked and viewed radiographically when positioned within the patient's body, thus allowing the physician to properly position the catheter which surrounds the stylet (abstract; col. 3, lines 10-18 in Thomas disclose that the radiopaque material is preferably barium sulfate and that this material is visualized radiographically in tracking the location of the device). The radiopaque material at the tip therefore is equivalent to the remotely detectable locator, as this is detected remotely (its position is detected and viewed on a monitor by the physician, which is obviously remote from the interior of the body in which the stylet is located). The radiographic system used by the physician and medical personnel to view the stylet is equivalent to the positioning system and image guided surgical workstation claimed, as this is a system used/viewed in surgery for positioning the stylet and catheter. Furthermore, the progress of the locator can be tracked and displayed by taking multiple radiographic images during it's travel through the body. While the examiner believes that it is obvious that a form of radiography used to track the device would also include displaying the resulting images on a monitor as part of an image guided workstation, such as in fluoroscopy, the Rosenman reference explicitly makes this connection obvious. Rosenman discloses a similar medical device that is tunneled through the body and includes a radiopaque marker on the device made from barium sulfate (paragraph [0042]; the same as the radiopaque marker used by

Thomas), and further discloses that the device is tracked radiographically by fluoroscopy (also in paragraph [0042]. It is well known to one of ordinary skill in the art at the fluoroscopy involves imaging the patient and the device within the patient and displaying the resulting images on the monitor of a surgical guided work station). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Elsberry with the remotely detectable radiopaque locator, as taught by Thomas and further supported by Rosenman, especially since Rosenman teaches the exact same type of radiopaque marker for imaging as is used in Thomas (paragraph [0042] in Rosenman), in order to provide a guiding and positioning system to properly and accurately position the catheter and stylet for treatment.

Claims 7 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elsberry in view of Thomas, further in view of Rosenman and further in view of Maginot et al. (US Patent No. 6,743,218). Elsberry in view of Thomas and further in view of Rosenman discloses the device substantially as claimed except for a clamp. Maginot, however, discloses a clamp (Fig. 3, 62 and 64) to be used at the proximal end of the catheter to prevent any fluid flow through the catheter system (col. 12, lines 12-18). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Elsberry in view of Thomas and further in view of Rosenman with the clamp as taught by Maginot in order to provide another mechanism in which stop the flow of fluid through the hollow tube.

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elsberry in view of Thomas, further in view of Rosenman and further in view of Hogan (US Patent No. 5,137,515). Elsberry in view of Thomas and further in view of Rosenman discloses the device substantially as claimed except for a cap and a plug at the end of the proximal tube. Hogan, however, discloses a cap (Fig. 1, 34) and plug (32) for the ends of a hollow tube (col. 3, lines 3-9). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Elsberry in view of Thomas and further in view of Rosenman with the cap and plug as taught by Hogan in order to provide mechanisms to seal the end of the hollow tube.

Response to Arguments

Applicant's arguments with respect to claims 1-4, 6-8, 11-25 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/
Examiner, Art Unit 3767

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772